

May 12, 2025

The Honorable Russell Vought
Director
Office of Management and Budget
725 17th St NW
Washington, DC 20503

RE: Request for Information: Deregulation

Dear Director Vought:

On behalf of the Home Care Alliance of Massachusetts (HCA)—the trade association representing nearly 200 home health, hospice, and home care providers (agencies) across the Commonwealth—we appreciate the opportunity to comment on the Office of Management and Budget's (OMB) Request for Information regarding federal regulatory reform.

Our member agencies provide essential services to some of the most vulnerable populations in Massachusetts, often allowing patients to remain safely at home instead of requiring costlier facility-based care. However, they operate under an increasingly complex and in many cases, duplicative regulatory framework that places undue administrative, financial, and operational burdens on providers. These constraints hinder innovation, limit access to care, and divert critical resources away from patient services.

We respectfully submit the following areas for federal review and reform:

I. Medicare Conditions of Participation and Benefit Requirements

Regulation: 42 CFR § 484.55(a) – Initial Assessment Requirements

Background:

This regulation requires that a registered nurse (RN) must conduct the initial assessment visit when nursing services are ordered. The rule does not allow other clinicians—such as physical therapists (PTs), occupational therapists (OTs), or speech-language pathologists (SLPs)—to complete the initial assessment, even if their services are also ordered and they are available to initiate care sooner.

Issue/Burden:

Given the severe and persistent shortage of RNs in the home health field, this regulation has become a major barrier to timely patient care. Agencies often have therapists ready and available to admit a patient, but must delay the start of care because an RN is not immediately available to conduct the assessment—even when therapy is the most clinically appropriate and urgently needed service.

This bottleneck not only disrupts operations but delays critical interventions that help patients recover from surgery, regain mobility, or prevent rehospitalizations. For example, a patient recovering from a joint replacement may need physical therapy within 24 hours, but the inability to assign a therapist to perform the initial assessment causes harmful delays.

Recommendation:

Reinstate the COVID-era flexibility that allowed PTs, OTs, and SLPs to conduct the initial assessment when nursing is ordered but not immediately available. This would enhance clinical appropriateness, improve timeliness of care, and reduce the strain on already overburdened nursing staff.

Regulation: 42 CFR § 484.55(a) – Initial Assessment Timing

This regulation requires that the initial assessment visit be completed within 48 hours of the referral, the patient's return home, or on the physician-ordered start-of-care date.

Issues:

- The 48-hour requirement is increasingly difficult to meet due to persistent nursing shortages and already full clinical schedules.
- Community-based referrals (as opposed to facility discharges) are particularly challenging to schedule quickly, as they are often less coordinated.
- Agencies are frequently unable to schedule a timely visit, resulting in administrative burdens such as notifying the community physician, confirming continued clinical appropriateness, and obtaining revised orders for a new start-of-care date.
- Delays in admission may contribute to prolonged hospital stays, increasing overall
 Medicare expenditures despite home health being the more cost-effective setting.

Recommendation:

CMS should expand flexibility around the 48-hour initial assessment requirement. We recommend allowing agencies, in collaboration with the referring physician, to determine whether a delayed admission is still clinically appropriate. This approach would reduce unnecessary administrative burden, support safe and timely admissions, and prevent avoidable hospital days that are more costly to the Medicare program.

Regulation: 42 CFR § 484.110(e) – Clinical Records

Background:

This regulation requires home health agencies (HHAs) to provide patients with a copy of their clinical record at no cost, either during the next home visit or within four business days of the request. Under Section 1135(b)(5) of the Social Security Act, CMS temporarily extended this timeframe to ten business days during the COVID-19 Public Health Emergency.

Issues:

- The four-day requirement can be difficult to meet, particularly for smaller HHAs that have limited administrative staff.
- Producing and delivering medical records within this short window diverts staff time away from direct patient care and imposes additional operational strain.
- The ten-day extension granted during the pandemic proved more manageable for agencies without compromising patient access to information.

Recommendation:

We recommend CMS reinstate the ten-business-day timeframe for providing clinical records to patients. This flexibility would better align with the operational capacity of small and mid-sized agencies, reduce administrative burden, and still ensure timely access to information for patients.

Regulation: 42 CFR § 424.22 – Face-to-Face (F2F) Encounter Requirement

Background:

The F2F encounter requirement mandates that a physician or qualified non-physician practitioner conduct and document a visit related to the patient's home health needs within a defined period prior to the start of care. While this provision is intended to ensure clinical necessity, its implementation has created significant administrative and operational challenges for providers.

We support the purpose of the Face-to-Face (F2F) encounter requirement, which is to verify that home health services are medically necessary. However, the associated documentation requirements are overly complex and place a disproportionate burden on home health agencies. Agencies must often 'chase' physicians for very specific details—such as explicit statements about the patient's homebound status and the need for skilled services—information that is not typically included in standard medical records.

Further complicating the issue, Medicare Administrative Contractors (MACs), such as National Government Services (NGS), frequently misinterpret the F2F documentation standards during audits, resulting in inappropriate denials of care. It is especially problematic that home health agencies are held financially accountable for documentation that only the physician can provide—despite physicians already being overwhelmed by administrative tasks. Because the

F2F is a condition of payment, this puts agencies at significant risk through no fault of their own.

Issue/Burden:

1. Overly Prescriptive Documentation Requirements:

Agencies frequently encounter claim denials not because the F2F encounter did not occur, but because the documentation lacks specific phrasing that explicitly links the visit to the patient's need for home health. This often necessitates repeated outreach to physicians to amend records—delaying billing and diverting staff time from care delivery.

2. Agency Accountability for External Documentation:

Agencies are held accountable for the structure and language of the physician's clinical documentation—something they do not control. This creates a compliance burden and places agencies at financial risk for services already rendered based on valid clinical need.

3. Pending Loss of Telehealth Flexibility:

The Congress has temporarily extended the ability to conduct F2F encounters via telehealth through September 30, 2025. While we appreciate this extension, it remains a time-limited waiver. Requiring in-person visits after this date will again impose serious barriers to access, especially for homebound patients with cognitive, behavioral, or mobility challenges, and in communities with transportation or clinician access limitations.

Recommendation:

- Allow physicians to satisfy the F2F requirement by attesting on the plan of care that the encounter occurred and was related to home health services.
- Focus audit protocols on whether the encounter occurred and was clinically appropriate, rather than requiring rigid narrative elements.
- Make telehealth a permanent option for satisfying the F2F requirement when conducted via compliant two-way audiovisual technology. This approach is not only practical but aligns with the realities of homebound populations and modern care delivery.

Regulation: 42 CFR § 484.105(i) – Acceptance-to-Service Policy

Background:

This newly added Condition of Participation (CoP) requires home health agencies to maintain and implement a formal policy describing the criteria for accepting or declining patient referrals.

<u>Issue/Burden:</u>

Nearly all established home health agencies already maintain internal procedures for screening and accepting patients. Adding a regulatory requirement to document and validate these existing practices introduces additional paperwork during survey processes without meaningfully improving patient care or operational standards.

The regulation also lacks flexibility for agencies operating under staffing constraints, which are currently the primary limiting factor in accepting new patients. Agencies may be forced to document "declinations" due to staffing even when demand far exceeds capacity—adding regulatory complexity to what is fundamentally a workforce issue.

Recommendation:

Rescind § 484.105(i) as redundant for agencies that already have clinical screening and referral policies in place. Alternatively, limit its application to newly certified agencies or those lacking a documented intake process.

Regulation: 42 CFR § 484.80(h)(2)(i) – Home Health Aide Supervision

Background:

In the 2022 Home Health Patient-Driven Groupings Model (HH PDGM) final rule, CMS revised the supervision requirements under § 484.80(h)(2)(i) for home health aides delivering only non-skilled services. The final regulation requires a registered nurse to conduct an **on-site supervisory visit at least every six months** to directly **observe and assess each aide with each individual patient** receiving care.

This represents a significant departure from CMS's original proposal. The proposed rule would have required registered nurses to perform on-site observations of home health aides while delivering care, but it did **not** mandate that such observations occur separately for **each patient** served by the aide.

The finalized rule introduced this narrower and more prescriptive interpretation without prior notice in the proposed rule—thereby depriving stakeholders of the opportunity to comment on the added specificity and scope. As a result, the final requirement imposes substantial administrative burden on home health agencies (HHAs), especially those with aides who serve multiple patients.

Issue/Burden:

- The requirement to observe home health aides individually with every patient they serve is both **redundant** and **disruptive**, increasing the workload for supervising nurses and intruding unnecessarily into patient care routines.
- It **does not improve the quality of care** or aide oversight beyond what was already achievable under CMS's original proposal.
- Agencies must allocate more time and resources to fulfill a requirement that exceeds the original regulatory intent, all without demonstrated clinical benefit.

Recommendation:

CMS should revise § 484.80(h)(2)(i) to align with the language originally proposed in the 2022 HH PDGM proposed rule, which more appropriately balances quality oversight with operational feasibility. The recommended language is:

"(ii) Semi-annually, the registered nurse must make an on-site visit to the location where a patient is receiving care in order to observe and assess each home health aide while he or she is performing non-skilled care."

Reverting to this original version would maintain essential supervisory oversight while reducing unnecessary regulatory burden and improving operational flexibility for home health agencies.

Regulation: 42 CFR § 484.55 – Outcome and Assessment Information Set (OASIS) Recommendation: Rescind Mandatory OASIS Collection for All Payers Background:

The Outcome and Assessment Information Set (OASIS) is a standardized clinical assessment tool used to support the Home Health Quality Reporting Program (HHQRP) and to determine reimbursement under the Patient-Driven Groupings Model (PDGM). Since its adoption in 2000, OASIS has played a central role in evaluating care quality and calculating Medicare payments for home health agencies (HHAs).

Historically, in response to congressional intervention, CMS suspended the requirement to collect OASIS data for patients not covered by Medicare or Medicaid. However, effective July 1, 2025, CMS will mandate that HHAs collect and report OASIS data for **all** patients, regardless of payer source—including those with private insurance or paying out-of-pocket.

Issue/Burden:

This policy change has generated significant concern within the home health industry due to the substantial and unfunded administrative burden it imposes.

- Financial and Operational Impact:
 Agencies will be required to complete and submit OASIS assessments for patients who
 are not part of Medicare or Medicaid programs, yet no reimbursement mechanism
 exists to cover these activities. As a result, HHAs will bear additional administrative
 costs, as well as indirect costs tied to the diversion of clinical resources from direct
- Workforce and Economic Pressures:

patient care to data collection and reporting tasks.

- The home health industry is already grappling with workforce shortages, Medicare payment reductions, and rising operational expenses. This expanded mandate exacerbates those challenges, placing further strain on a sector already stretched thin. Rural providers are expected to experience disproportionate hardship due to:
 - Longer travel distances to reach patients in remote areas.
 - Increased difficulty in recruiting and retaining qualified clinical staff.

CMS itself anticipates that this change will lead to a **30% increase in the number of OASIS assessments** required at each data collection interval. The agency projects the annual implementation cost to HHAs will exceed **\$267.2 million**, beginning in calendar year 2025.

Recommendation:

CMS should rescind the requirement for HHAs to collect and report OASIS data for non-Medicare and non-Medicaid patients. The reporting obligation should remain limited to Medicare and Medicaid beneficiaries—populations for which the tool was specifically designed and validated. Maintaining the current, targeted scope of data collection will ensure continued oversight of care quality while avoiding unnecessary financial and administrative burdens on providers, particularly those serving vulnerable and underserved communities.

Recommendation: Modify CMS Policy for New Certifications Triggered by Start of Care (SOC) OASIS

Background:

Under current CMS policy, a new physician certification is required each time a Start of Care (SOC) OASIS is submitted—even when the change in patient status is purely administrative. This frequently occurs when a beneficiary transitions from one payer source to another, such as moving from a Medicare Advantage plan to Traditional Medicare.

In these situations, the patient's **plan of care remains unchanged**. The same physician continues to oversee treatment, and there is no alteration in the patient's condition or clinical needs. Nevertheless, the HHA must initiate a new certification and complete redundant intake documentation simply because of a payer transition.

Issue/Burden:

Requiring a new certification in these circumstances imposes avoidable documentation workload on clinicians and administrative staff. It also introduces unnecessary complexity into the billing and care coordination processes, especially when no substantive change in services has occurred.

Recommendation:

CMS should revise its policy to **make new certifications optional** when a Start of Care OASIS is completed solely for administrative reasons and the patient remains on the same uninterrupted plan of care. This targeted change would reduce paperwork burden and support continuity of care without compromising regulatory oversight.

Recommendation: Reducing the OASIS Documentation Burden in Home Health Care <u>Issue Summary</u>

The Outcome and Assessment Information Set (OASIS) is a federally mandated tool used for patient assessment and quality reporting in home health. While essential for compliance, payment, and oversight, the current OASIS structure places an excessive documentation burden on clinicians, reducing efficiency, increasing burnout, and limiting time spent on direct patient care. Reform is urgently needed.

Policy Ask

Streamline and modernize OASIS data collection by:

• Eliminating redundant or low-value items

- Aligning documentation requirements with clinical relevance
- Incorporating technological solutions to automate data entry

These reforms will improve care delivery, clinician well-being, and system efficiency without compromising regulatory integrity.

Why It Matters

1. Administrative Burden Harms Efficiency

- Clinicians spend 60–90+ minutes per OASIS assessment, diverting time from patient care.
- Many OASIS items are not essential for care planning, payment, or quality measures.
- Streamlining would reduce documentation time and improve operational flow.

2. Clinician Burnout and Workforce Crisis

- Documentation burden is a leading driver of burnout and attrition in home health.
- Clinicians report less time for patient education and engagement due to paperwork demands.
- A simplified OASIS would support workforce sustainability in a critical care sector.

3. Patient Care Is Compromised

- Excessive data entry reduces the time available for hands-on care and personalized attention.
- Less documentation means more time at the bedside and improved patient satisfaction.
- Outcomes improve when clinicians can focus on clinical decision-making over compliance tasks.

4. Data Quality and Usefulness

- Research shows a significant portion of OASIS elements are underused or duplicative.
- Streamlining supports cleaner, more actionable data for risk adjustment and care coordination.
- A modernized OASIS would enhance interoperability with EHRs and reduce input errors.

5. Policy Momentum and Alignment

- CMS has recognized the burden of documentation through initiatives like Patients Over Paperwork.
- Modern care models (e.g., value-based purchasing) demand leaner, smarter data systems.

 Reforming OASIS aligns with national goals to reduce clinician burden and enhance care quality.

Recommended Actions

- Conduct a formal review of OASIS data elements with stakeholder input (clinicians, agencies, policymakers).
- Phase out non-essential fields that do not directly impact care planning, payment, or outcomes.
- Pilot test a reduced-data model across diverse agencies to evaluate impact and feasibility.
- Support EHR vendors and providers in implementing streamlined workflows and automation tools.

Reducing the OASIS documentation burden is a common-sense, evidence-backed reform that will strengthen home health care delivery. By streamlining data requirements, policymakers can enable clinicians to do what they do best: provide high-quality, person-centered care in the home.

Regulation: Medicare Benefit Policy Manual, Chapter 7, Section 30.4 – Qualifying Disciplines Background:

Currently, a patient must require skilled nursing or physical therapy to qualify for the Medicare home health benefit. Occupational therapy (OT), despite being a critical and highly skilled service, cannot serve as the sole qualifying discipline for initiating care.

Issue/Burden:

This exclusion creates significant access barriers for patients whose primary needs are functional—such as assistance with bathing, dressing, toileting, or using adaptive devices—and best addressed by an occupational therapist. These patients are homebound and in need of skilled care, but are denied access or forced to wait until another qualifying service is ordered—even when that service is not clinically indicated.

This policy results in delayed care, increased costs, and poor alignment of patient needs with the service provided. It also exacerbates staffing challenges by requiring agencies to deploy nurses or PTs for the sole purpose of establishing eligibility, even when OT is the most appropriate discipline.

Recommendation:

Update Medicare policy to allow OT to independently establish eligibility for the home health benefit when appropriate. Doing so would promote timely access to care, reduce administrative inefficiencies, and ensure patients receive the most suitable services without delay.

Regulation: Electronic Visit Verification (EVV) – 21st Century Cures Act Preliminary Statement:

While we recognize that the federal mandate for Electronic Visit Verification (EVV) is statutory, in Section 1903(I) of the Social Security Act and not subject to repeal through this process, we strongly urge OMB to assess and address the deeply flawed mechanisms states are using to implement it. It is not the verification of visits that we question—it is the unwieldy, resource-intensive, and error-prone processes required to demonstrate compliance. The law states, (1903(I)(2)(A)(i) of the Act requires the state to implement a system that, "is minimally burdensome." In Massachusetts, as in many states, these processes have created significant administrative and financial burdens, particularly for small and mid-sized agencies which are already under resourced. The current implementation model risks undermining the very goal of program integrity by making compliance so difficult that providers are left demoralized and disadvantaged.

Issue/Burden:

1. Administrative Overhead and Staffing Impact

Massachusetts offers a "free" EVV system through HHAeXchange, but the technical and procedural complexity of using it has forced agencies to hire new administrative staff or divert clinical managers from patient care to manage EVV data validation, error resolution, and submission. While frontline staff may correctly enter the required six data elements (type of service, recipient, caregiver, time in/out, date, and location), agencies still face hurdles in ensuring the data is formatted and transmitted exactly as the state system requires. This has turned a compliance task into an operational burden.

2. Cost of Alt-EVV and Vendor Limitations

Although Massachusetts permits agencies to use their own system (Alt-EVV), the majority of providers—particularly smaller agencies—did not have EVV capability built into their existing medical record platforms. Many have had to purchase EVV modules or separate software at costs upwards of \$10,000, in addition to incurring ongoing integration and support fees. This expense is not reimbursed, and in an environment where agencies already deliver care at a loss, it only exacerbates financial strain. For others, working through clunky software bridges or spreadsheets has proven unreliable, often triggering compliance failures due to formatting errors.

3. Technological and Geographic Challenges

Connectivity remains a serious challenge, especially in rural or semi-rural areas of Massachusetts. Clinicians often cannot complete real-time verification due to limited cellular or internet access. Even urban areas are not immune—connectivity gaps have been reported in apartment buildings, basements, and public housing units. Despite these limitations, agencies are still expected to meet real-time submission standards, which can result in flags, denials, or

follow-up audits for what are essentially infrastructure shortcomings outside the agency's control.

Recommendations:

- Simplify the process for correcting demographic mismatches by allowing providers (with consent) to work directly with the state to resolve errors that prevent data transmission.
- Provide implementation funding or grants to offset the cost of Alt-EVV adoption, especially for agencies that did not have EVV functionality embedded in their original systems.
- Allow offline verification methods for areas with unreliable internet or cellular service, enabling later synchronization without penalties. Or remove mandates that establish minimum thresholds of provider claims with EVV data in certain instances.
- Explore phased or retrospective verification models that still protect against fraud but reduce real-time technical pressure on agencies.

We support the principle of visit verification as a tool for program integrity, but the current structure imposes excessive cost, complexity, and unworkable requirements. We urge OMB to work with CMS and states to streamline EVV compliance processes, eliminate unreasonable restrictions on provider support, and ensure that the statutory requirement can be met in a way that is both effective and sustainable for home-based care providers.

2024 Final Medicaid Access Rule

The final 2024 Medicaid Access Rule established a policy requiring providers of home health aide, homemaker, and personal care services to allocate 80% of Medicaid Revenues on compensation to the direct care workers beginning in 2030 (42 CFR §441.301(k)). While we agree with the rationale that the direct care workforce must be compensated more adequately, the policy's structure would lead to significant disruption and reductions in access to care.

Current Medicaid provider payment rates are established on a state-by-state basis, and most states – including Massachusetts – have reimbursement rate setting processes that lack clarity, logic and are rarely adjusted in a way that covers a provider's cost of delivering services. CMS acknowledges this in other aspects of the Access Rule – which established requirements for states to adhere to in determining reimbursement rates. In addition – the rule is unworkable in its current form due to its narrow definition of compensation and direct versus indirect cost.

Lastly, there is considerable and legitimate industry concern that the regulation was established without legal authority.

Recommendation:

Rescind the Payment Adequacy Provision at 42 CFR §441.301(k), the reporting requirements at 42 CFR §441.311(e), and all associated requirements for sections 1915(i), 1915(j), and 1915(k) benefits, which are located at 42 CFR §§441.302(k), 441.464(f), 441.570(f), and 441.745(a)(1)(vi).

Recommendation: Redundancy Between Federal and State Medicare/Medicaid Cost Reports

<u>Regulation:</u> CMS Medicare Cost Report (CMS-1728-94 for home health) and State Medicaid Cost Reports

<u>Burden</u>: Agencies must prepare and submit nearly identical financial and operational data to both CMS and state Medicaid programs. These parallel reporting structures often require different formats or platforms, doubling the administrative effort with no added value.

<u>Recommendation</u>: CMS and state Medicaid programs should coordinate to allow for shared use of a single cost report or harmonized reporting platform. This would reduce duplication and allow agencies to focus more resources on patient care.

Regulation: U.S. Census Bureau's Annual Integrated Economic Survey (AIES)

<u>Burden:</u> This annual data request demands highly detailed business, financial, and operational data from providers. It is time-consuming to complete, costly in terms of labor, and of unclear utility to agencies. Smaller home care providers often lack the internal resources to complete this survey without outsourcing.

<u>Recommendation:</u> OMB should evaluate the necessity of full-sector reporting for healthcare providers and consider a stratified random sampling approach. Guidance and data templates should be simplified to reduce administrative complexity.

Duplication Between OSHA and BLS Injury/Illness Reporting

Regulations: OSHA Injury and Illness Recordkeeping (29 CFR Part 1904) and BLS Survey of Occupational Injuries and Illnesses (SOII)

<u>Burden:</u> Employers, including home health agencies, are required to maintain OSHA Form 300 logs, post annual summaries (Form 300A), and submit data electronically. BLS then surveys many of the same agencies, requesting the exact same data for statistical purposes. This redundant reporting process burdens staff with duplicative tasks.

<u>Recommendation</u>: OMB should direct OSHA and BLS to develop an integrated reporting framework or establish inter-agency data sharing protocols to eliminate redundancy.

Regulation: Section 1557 of the Affordable Care Act, Final Rule (HHS, May 2024, 45 CFR Part 92)

<u>Burden</u>: The rule mandates agencies implement new nondiscrimination policies, designate a compliance coordinator, provide translated materials, update websites, and train staff on culturally competent care and civil rights protections by July 5, 2025. These requirements are resource-intensive, particularly for small agencies that do not have legal or compliance departments. Many providers report confusion over the scope of changes required and high implementation costs.

<u>Recommendation</u>: HHS should offer model templates, technical guidance, and compliance toolkits specifically tailored to small and mid-sized providers. OMB should consider a tiered implementation timeline based on agency size and capacity.

Closing Remarks and Call to Action

The Home Care Alliance of Massachusetts appreciates the Office of Management and Budget's efforts to review and reduce unnecessary or duplicative regulatory requirements. We strongly support initiatives that promote regulatory efficiency while preserving patient safety and program integrity.

We urge OMB to consider the recommendations outlined above, which reflect the real-world challenges faced by home health agencies across Massachusetts. These changes would meaningfully reduce the administrative burden, allowing providers to focus more fully on delivering high-quality care in the home.

We welcome the opportunity to engage further as a stakeholder representing the care-at-home community and stand ready to support future efforts aimed at aligning federal requirements with practical, patient-centered care delivery.

Thank you for your time and thoughtful consideration.

Sincerely,

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